

RECEIVED 010/018
CENTRAL FAX CENTER
JUN 19 2008

Application No. 10/762,421
Amendment dated June 19, 2008
Reply to Office Action of December 19, 2008

Docket No.: CDSI-P01-040

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising a carbonic anhydrase inhibitor and a matrix material wherein said carbonic anhydrase inhibitor is admixed in the matrix material to inhibit or prevent decomposition of the carbonic anhydrase inhibitor;
- (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the carbonic anhydrase inhibitor, having one or more openings therein which permit diffusion of the carbonic anhydrase inhibitor, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and
- (iii) one or more additional coatings that are permeable to the passage of the carbonic anhydrase inhibitor, ~~and which~~ are substantially insoluble and inert in body fluids and compatible with body tissues and comprise a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core;

wherein the first and additional coatings are disposed about the inner drug core so as to produce, when implanted, a substantially constant rate of release of the carbonic anhydrase inhibitor from the device.

2. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising a carbonic anhydrase inhibitor and a matrix material wherein said carbonic anhydrase inhibitor is admixed in the matrix material to inhibit or prevent decomposition of the carbonic anhydrase inhibitor;
- (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the carbonic anhydrase inhibitor, having one or more openings therein which permit diffusion of the carbonic anhydrase inhibitor, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and

Application No. 10/762,421
Amendment dated June 19, 2008
Reply to Office Action of December 19, 2008

Docket No.: CDSI-P01-040

- (iii) one or more additional coatings that are permeable to the passage of the carbonic anhydrase inhibitor, ~~and which~~ are substantially insoluble and inert in body fluids and compatible with body tissues and comprise a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core;

wherein the impermeable coating has sufficient dimensional stability to be filled with a carbonic anhydrase inhibitor core without changing its shape.

3. (Original) The device of claim 1, wherein the impermeable coating has sufficient dimensional stability to be filled with a carbonic anhydrase inhibitor core without changing its shape.

4. (Withdrawn) A method for administering a carbonic anhydrase inhibitor to the ciliary body of an eye, the method comprising implanting a sustained-release device in or adjacent to the eye, whereby the device delivers the carbonic anhydrase inhibitor to the ciliary body of the eye, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 30 days.

5. (Withdrawn) A method for administering a carbonic anhydrase inhibitor to the ciliary body of an eye, the method comprising implanting a sustained-release device according to any one of claims 1-3 or claim 14 in or adjacent to the eye, whereby the device delivers the carbonic anhydrase inhibitor to the ciliary body of the eye, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 30 days.

6. (Withdrawn) The method of claim 4, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 180 days.

Application No. 10/762,421
Amendment dated June 19, 2008
Reply to Office Action of December 19, 2008

Docket No.: CDSI-P01-040

7. (Withdrawn) The method of claim 5, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 180 days.

8. (Withdrawn) The method of claim 4, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.

9. (Withdrawn) The method of claim 5, wherein the carbonic anhydrase inhibitor concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.

10. (Currently Amended) The device according to any one of claims 1-3 ~~4, 6, and 8~~, wherein the carbonic anhydrase inhibitor is selected from acetazolamide, methazolamide, ethoxzolamide, dichlorphenamide, dorzolamide, and brinzolamide.

11. (Withdrawn) The method according to claim 5, wherein the carbonic anhydrase inhibitor is selected from acetazolamide, methazolamide, ethoxzolamide, dichlorphenamide, dorzolamide, and brinzolamide.

12. (Withdrawn) The method according to claim 7, wherein the carbonic anhydrase inhibitor is selected from acetazolamide, methazolamide, ethoxzolamide, dichlorphenamide, dorzolamide, and brinzolamide.

13. (Withdrawn) The method according to claim 9, wherein the carbonic anhydrase inhibitor is selected from acetazolamide, methazolamide, ethoxzolamide, dichlorphenamide, dorzolamide, and brinzolamide.

Application No. 10/762,421
Amendment dated June 19, 2008
Reply to Office Action of December 19, 2008

Docket No.: CDSI-P01-040

14. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising at least one carbonic anhydrase inhibitor and a matrix material wherein said carbonic anhydrase inhibitor is admixed in the matrix material to inhibit or prevent decomposition of the carbonic anhydrase inhibitor;
- (ii) a coating layer on the surface of the drug core that is partially or substantially impermeable to the passage of the at least one carbonic anhydrase inhibitor, having one or more openings therein which permit diffusion of the carbonic anhydrase inhibitor, and that is substantially insoluble and inert in body fluids and compatible with body tissues; and comprises a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core;

wherein the coating is disposed about the inner drug core so as to produce, when inserted a substantially constant rate of release of the carbonic anhydrase inhibitor from the device.

15. (Cancelled)

16. (Previously Presented) The sustained release drug delivery device of claim 14, wherein the polymer matrix is bioerodible.

17. (Original) The sustained release drug delivery device of claim 14, wherein the device is formed by co-extruding the inner drug core and the coating layer.

18. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising at least one carbonic anhydrase inhibitor and a matrix material wherein said carbonic anhydrase inhibitor is admixed in the matrix material to inhibit or prevent decomposition of the carbonic anhydrase inhibitor;
- (ii) a coating layer on the surface of the drug core that is partially or substantially permeable to the passage of the at least one carbonic anhydrase inhibitor, having one or more openings therein which aid diffusion of the at least one carbonic

Application No. 10/762,421

Docket No.: CDSI-P01-040

Amendment dated June 19, 2008

Reply to Office Action of December 19, 2008

anhydrase inhibitor, and that is substantially insoluble and inert in body fluids and compatible with body tissues; and comprises a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core;

and wherein the coating is disposed about the inner drug core so as to produce, when inserted, a substantially constant rate of release of the at least one carbonic anhydrase inhibitor from the device.

19. (Cancelled)

20. (Previously Presented) The sustained release drug delivery device of claim 18, wherein the polymer matrix is bioerodible.

21. (Original) The sustained release drug delivery device of claim 20, wherein the device is formed by co-extruding the inner drug core and the coating layer.